

Notice of Allowability	Application No.	Applicant(s)	
	10/017,822	ZINKOWSKI ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/25/03.
2. ☒ The allowed claim(s) is/are 32-33 and 35-37, renumbered as 1-5 respectively.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT & REASONS FOR ALLOWANCE

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven J. Sarussi on 1/9/04.

An examiner's amendment to the record appears below.

In the specification:

Inserted as the first sentence of the specification:

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--This application is a continuation of United States Patent Application No. 09/334,582, filed June 16, 1999, now abandoned.--

In the claims:

Canceled claims 1-31 and 34.

Amended claim 32:

32. (Amended) A method for detecting autoantibodies that are present in Alzheimer's disease comprising:

- (a) obtaining a protein preparation [according to claim 1] consisting essentially of an antigen that is immunologically reactive with a monoclonal antibody produced by the hybridoma cell line identified as ATCC No. HB9205, said preparation being substantially free of immunoglobulin G, a bovine microtubule associated protein preparation, and a sample being tested for the presence of said autoantibodies;
- (b) electrophoresing said protein preparation and said bovine microtubule associated protein preparation on separate lanes on a gel;
- (c) transferring said electrophoresed protein preparation and said bovine microtubule associated protein preparation to a membrane;
- (d) contacting said membrane with a sample being tested for the presence of said autoantibodies such that an autoantibody complex can form with antigen present in said protein preparation and/or with antigen present in said bovine microtubule associated protein preparation; and
- (e) detecting said autoantibodies by the formation of said complex(es).

Amended claim 33:

33. (Amended) A method for detecting autoantibodies that are present in Alzheimer's disease comprising:

- (a) obtaining a protein preparation [according to claim 1] consisting essentially of an antigen that is immunologically reactive with a monoclonal antibody produced by the hybridoma cell line identified as ATCC No. HB9205, said preparation being substantially free of immunoglobulin G and [or] a bovine microtubule associated protein preparation;
- (b) contacting said protein preparation and [or] said bovine microtubule associated protein preparation with a sample being tested for the presence of said autoantibodies such that an antigen-autoantibody complex can form; and
- (c) detecting said autoantibodies by the formation of said complex.

The following is an examiner's statement of reasons for allowance: the closest prior art of record is US 5,492,812 ("Vooheis"). Vooheis discloses methods using purified tau-proteins or fragments thereof to detect autoantibodies from blood or spinal fluid from patients suffering from Alzheimer's disease (column 15, line 64 to column 16, line 16). However, Vooheis does not disclose or render obvious methods using bovine microtubule associated protein preparations in conjunction with a protein preparation consisting essentially of an antigen that is immunologically reactive with a monoclonal antibody produced by the hybridoma cell line identified as ATCC No. HB9205, said preparation being substantially free of immunoglobulin G.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

1/9/04

Gary D. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600